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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 02/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/292,758

Applicant(s)

BURMER ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,7,9,10,29 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,7,9 and 10 is/are rejected.
- 7) ☒ Claim(s) 29 and 31-33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 2, 3, 7, 9, and 10 of this application. The specification of the provisional application has not been found to provide an adequate written description of the innumerable nucleic acids claimed nor a sufficient description of same such that one would be able to distinguish members of the genera from non-members.

Claim Objections

2. Claims 29-33 are objected to because of the following informalities: The amendment of 02 December 2002 indicated that a typographical error had been made in the claim wherein SEQ ID NO:38 had been identified and that SEQ ID NO.: 37 was intended. A review of the disclosure finds that both SEQ ID NO.: 37 and 38 are drawn to nucleic acid sequences and that the response of October 16, 2000 clearly states: "Applicants elect the following 10 nucleic acid species for examination: SEQ ID NO:1, 2, 6, 38, 55, 61, 69, 70, and 73." While applicant may now wish, some two years later, that another sequence be examined, applicant has received an examination on the merits for the ten sequences that they have elected. The amendment, therefore, is considered to introduce non-elected subject matter into claims 29-33. Appropriate correction is required.

- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, 3, 7 and 9 are drawn to broad genera of nucleic acid molecules. In the case of claims 2 and 3, the claimed nucleic acids are to have from 85% to 95% “sequence identity” with SEQ ID NO. 1. And in the case of claims 7 and 9, the claimed nucleic acids are to have from 85% to 95% sequence identity to that of SEQ ID NO.: 2. And in all instances, the claimed nucleic acids are to be “associated with the senescence of a cell.” A review of the Sequence Listing finds that SEQ ID NO.: 1 is 538 nucleotides in length while SEQ ID NO.: 2 is 338 nucleotides in length. Using the fixed percentages of 85% and 95% and excluding any and all intervening percentages (between 85% and 100%) and using only the 20 classical amino acids for substitution, it is readily determined that there are

[illegible]

000 nucleic acids that have 95% sequence identity with SEQ ID NO.:1. In looking at claims 9 and 10, it is found that there are

[illegible][illegible]

000000000000000000000000 sequences that have 85% sequence identity with SEQ ID NO.:2

[illegible]

sequence identity with SEQ ID NO.:2. The teaching by the specification of but two sequences

does not reasonably suggest that applicant was in possession of the claimed genus at the time of

filing. Additionally, the specification does not provide an adequate written description such that

the skilled artisan would be readily able to differentiate between the nucleic acids that are

encompassed by the claims and those that are not. In support of this position, attention is

directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In *re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In *re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

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For the above reasons, and in the absence of convincing evidence to the contrary, claims 2, 3, 7 and 9 are rejected under 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 2, 3, 7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene.

8. For purposes of examination, claims 2, 3, 7, 9, and 10 have been interpreted as encompassing nucleic acids of virtually length.

9. Stratagene discloses isolated nucleic acids (random primers) of 9 nucleotides in length. Such isolated nucleic acids are considered to comprise sequences that have 100% sequence identity to the claimed sequence. Accordingly, such sequences also are associated with cell senescence as a compound and its properties are inseparable. Such sequences fairly anticipate the nucleic acids of claims 2, 3, 7, 9, and 10.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
February 5, 2003